

REMARKS

Claims 1-25 are pending. By this amendment, claims 1-6, 7, 13, 15, 17, 19 and 22-25 are amended. No new matter has been added by these amendments.

Claim Rejections – 35 USC § 102

Claims 1, 2 and 6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,745,023 to Greenberg et al. Applicant has amended independent claim 1 to pertain to an ingestible drug substance as discussed during the interview of August 24, 2004. Support for the amendment to claim 1 is found at Page 7, Lines 18-22 referring to active ingredients including “freeze-dried probiotic microorganisms, antibiotics, oil soluble, and water soluble vitamins, enzymes such as Papain, salts of bioactive ingredients such as glucosamine hydrochloride, glucosamine sulfate, and chondroitin sulfate, polysaccharides, fructooligosaccharides and/or combinations thereof.” Applicant respectfully asserts that one or more of the specified active ingredients meet the definition for the term “drug” as defined at Section 201(g)(1) of the Federal Food, Drug, And Cosmetic Act. A copy of said section is attached herein. Based on the amendment to independent claim 1, Applicant respectfully requests that the rejection by Greenberg et al. be withdrawn as previously agreed.

Claims 1-3, 6-9, 12 and 13 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,913,921 to Schroeder et al. Applicant has amended independent claims 1 and 7 to further define the present invention as describing a palatable viscous carrier protecting a degradable, ingestible drug substance (Amended Claim 1) or a degradable, ingestible probiotic ingredient (Amended Claim 7) from exposure to external factors so as to prevent degradation.

Applicant respectfully asserts that Schroeder et al. does not disclose such a palatable viscous carrier protecting either a degradable, ingestible drug substance or a degradable, ingestible probiotic ingredient from exposure to external factors.

Schroeder et al. discloses a food product utilizing fructose to stabilize fish oils so as to avoid flavor and odor degradation of the fish oils. Nowhere does Schroeder et al. describe the use of a palatable viscous carrier as protecting either a degradable, ingestible drug substance or a degradable, ingestible probiotic ingredient from exposure to external factors. Furthermore, Schroeder et al. explicitly describes fish oil as being “highly unstable” (See Abstract, Col. 3, Lines 62-68; Col. 4, Lines 20-22, 39-41) and it being **essential** that the composition comprise fructose to as to realize the oil stability advantages describe. As such, it could not be reasonably inferred from a review of Schroeder et al. that a fish oil mixture lacking fructose would have any beneficial stability properties. As Schroeder et al. fails to disclose a palatable viscous carrier protecting either a degradable, ingestible drug substance or a degradable, ingestible probiotic ingredient from exposure to external factors, Schroeder et al. cannot anticipate amended claims 1 and 7. By definition, Schroeder et al. cannot anticipate dependent claims 3, 6, 8, 9, 12 and 13 which depend from claims 1 and 7. As such, Applicant respectfully requests said rejections be withdrawn.

Claim Rejections – 35 USC § 103

Claims 1, 2, 6-8, 12-16 and 19-24 were rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,010,720 to Derrieu et al., in view of Greenberg et al. As discussed previously, Applicant has amended independent claims 1 and 7 to further define the

present invention as describing a palatable viscous carrier protecting a degradable, ingestible drug substance (Amended claim 1) or a degradable, ingestible probiotic ingredient (Amended claim 7) from exposure to external factors so as to prevent degradation. In addition, claim 19 has been amended to define a method for preparing an ingestible, hydrophobic gel matrix containing probiotic substances. The Applicant respectfully submits that the combination of Derrieu et al, and Greenberg et al. under 35 USC § 103(a) is improper and even when combined, fails to disclose the subject matter of presently amended independent claims 1, 7 and 19.

Prima facie obviousness is not established if all the elements of the rejected claim are not disclosed or suggested in the cited art. In re Ochiai, 37 USPQ 1127, 1131 (Fed. Cir. 1995). ("The test for obviousness *vel non* is statutory. It requires that one compare the claims' 'subject matter as a whole' with the prior art 'to which said subject matter pertains.'"). See also, MPEP 2143.03 "All Claim Limitations Must Be Taught or Suggested," citing In re Royka, 180 USPQ 580 (CCPA 1974). "To establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art." MPEP 2143.03. Furthermore, the claimed invention taken as a whole cannot be said to be obvious without some reason given in the prior art why one of ordinary skill would have been prompted to combine the teachings of the references to arrive at the claimed invention. In re Regal, 188 USPQ 132 (CCPA 1975). A criteria to establish a *prima facie* case of obviousness is that there must be some suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine the reference teachings. MPEP 2142-2143. In re Vaeck, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991).

Applicant submits that there is no motivation to combine the Derrieu et al. reference with the Greenberg et al. reference. First, Greenberg et al. describes a pet food composition for improving flavor and enhancing appetite while Derrieu et al. relates to the oral delivery of chemicals and medicaments. Second, the Derrieu et al. reference and Greenberg et al. reference disclose two distinct forms of delivery. Derrieu et al discloses a palatable composition in a solid form (see Page 2, Lines 51-52; see claim 1) while Greenberg et al. discloses a clear, liquid composition (see Abstract; see Page 2, lines 58-63; see Page 4, lines 16-22; see claim 1). There is no suggestion within either reference that a combination of the solid form of Derrieu et al. and the liquid form of Greenberg et al. would lead to either a palatable viscous carrier or an ingestible, hydrophobic gel matrix for use in protecting and delivering ingestible substances.

Even if combined, the combination of Derrieu et al. and Greenberg et al. fails to disclose a palatable viscous carrier protecting a degradable, ingestible drug substance (Amended claim 1) or a degradable, ingestible probiotic ingredient (Amended claim 7) from exposure to external factors so as to prevent degradation. Furthermore, the combination of Derrieu et al. and Greenberg et al. fail to disclose a process step of cooling a natural oil mixture to form an ingestible, hydrophobic gel matrix (Amended claim 19).

Applicant respectfully submits that the Examiner has failed to establish a case for *prima facie* obviousness and requests that the rejection of independent claims 1, 7 and 19 under 35 USC § 103(a) be withdrawn. For the same reasons, Applicant also requests the rejections to dependent claims 2, 6, 8, 12-16 and 20-24 be withdrawn as well.

Claims 4, 5, 10 and 11 were rejected under 35 USC § 103(a) as being unpatentable over Derrieu et al. and Greenberg et al. in view of U.S. Patent No. 4,867,986 to Desai et al. Applicant

respectfully traverses said rejections as the Desai et al. reference fails to cure the aforementioned and discussed deficiencies of the combination of Derrieu et al. and Greenberg et al. Desai et al. describes a microemulsified composition in which marine oil compositions, containing Omega-three fatty acids, are protected from exposure oxygen by a gelatin micro-emulsifier. The composition of Desai et al. explicitly teaches away from protecting a probiotic substance (Claims 7 and 19) or a ingestible drug substance (Claim 1) with a palatable viscous carrier comprising in part fish oil. In general, a reference may be said to teach away from its combination with a second reference if a person of ordinary skill in the art, upon reading the first reference, would be led in a direction divergent from the path that was taken by the Applicant. In re Gurley, 27 F.3d 551, 31 USPQ 2d 1130 (Fed. Cir. 1994). A person of ordinary skill in the art would, upon a reading of Desai et al., be directed away from such a palatable viscous carrier comprising fish oil for fear of exposing the fish oil to oxygen. As such, Applicant respectfully suggests that Desai et al. fails to cure the deficiencies of Derrieu et al. and Greenberg et al. relative to independent claims 1, 7 and 19 and as such, Applicant requests the rejections to dependent claims 4, 5, 10 and 11 be withdrawn.

The Examiner rejected claims 17, 18 and 25 under 35 USC § 103(a) as being unpatentable over Derrieu et al. and Greenberg et al. and in view of U.S. Patent No. 4,518,696 to Gehrman et al. Applicant respectfully traverses said rejections as the Gehrman et al. reference fails to cure the aforementioned and discussed deficiencies of the combination of Derrieu et al. and Greenberg et al. Gehrman et al. discloses a sunflower seed oil suspension for administration to an animal. Gehrman et al. teaches away from the palatable viscous carrier of claim 7 by teaching that sunflower seed oil is preferably the "**only**" liquid ingredient of the medium (Col. 2,

Lines 61-63) and by disclosing testing of the preservation properties of other oils that lead to the conclusion that, "...sunflower oil has special properties for maximizing the preservation of Lactobacilli in oil suspension." Col. 5, Lines 21-23. Combining Gehrman with Derrieu et al. and Greenberg et al. would nullify the desired invention of Gehrman, i.e., a suspension medium having sunflower oil as its only liquid. It would also be contrary to the teaching of Gehrman which explicitly categorizes sunflower oil, as having special, advantageous preservation properties. As such, Gehrman et al. teaches away from the Examiner's suggested combination. In light of Gehrman et al., it cannot reasonably be said that a person skilled in the art would infer that combining Gehrman with Derrieu et al. and Greenberg et al. would result in the formulation of a palatable viscous carrier for protecting, degradable, ingestible probiotic ingredients (claim 7) and furthermore, one of skill in the art would be lead away from heating a combination of vegetable and fish oils (claim 19) not to tabilized and shelf-stable mixture in light of the special preservation properties of sunflower oil as described by Gehrman. Instead, a person of reasonable skill in the art would avoid combining Gehrman with Derrieu et al. and Greenberg et al for fear of detrimentally effecting the special preservation properties of sunflower oil as described by Gehrman et al. As such, Applicant respectfully suggests that Gehrman et al. fails to cure the deficiencies of Derrieu et al. and Greenberg et al. relative to independent claims 7 and 19 and as such, Applicant requests the rejections to dependent claims 17, 18 and 25 be withdrawn.

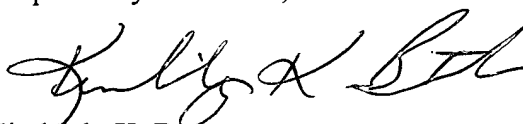
CONCLUSION

In view of the foregoing, it is submitted that this application is in condition for allowance.

Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Kimberly K. Baxter', written in a cursive style.

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